

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 5 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruitt (US 6458076 B1) in view of Hirata (US 7591781 B2).**

3. Regarding claim 5, Pruitt teaches

an internal treatment apparatus for a patient comprising a flexible tubular body [14] to be introduced into a patient, said flexible tubular body comprising:

a center opening [20'] capable of inserting therethrough an endoscope for observing a target site, said center opening extending through said flexible tubular body from a center of a distal end face of said flexible tubular body [Fig. 5], said distal end face facing said target site and a plurality of circumferential holes [e.g. 21'-28'] through which surgical instruments can be inserted for performing a surgical procedure on said target site, each of the holes being distinct from the center opening. However, Pruitt fails to specifically teach the holes provided to extend through a side face [Figs. 9A, 9B] of said flexible tubular body at said distal end of said flexible tubular body and independent from the distal end face.

Hirata teaches a flexible internal treatment apparatus having a plurality of lumens [91a] for inserting tools into a body lumen for treatment, wherein the outlets, which are

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plurality of circumferential holes [98a-c], are placed on lateral sides of a distal end of the apparatus [Fig. 9A, the distal end face being unlabeled solid end piece] such that tools inserted within the lumens can be extended from the sheath at any desired position in order to inspect other portions of the body lumen [col. 8, ll. 41-60].

It would have been obvious to one of ordinary skill in the art to modify the apparatus as taught by Pruitt with lateral circumferential holes as taught by Hirata to provide the additional advantage of allowing inserted tools to be extended from the tubular body in additional positions in order to allow for more flexible and varied treatment.

Regarding claim 35, Pruitt in view of Hirata teach the flexible tubular body comprises a resiliently deflectable portion [14, 16, Fig. 1 of Pruitt], and a circumferential opening portion [where the holes of Hirata are located on Pruitt] includes said plurality of circumferential holes, and the circumferential opening portion passes through the apparatus body from a side face of the deflectable portion toward a proximal end face of the apparatus body [as seen in Hirata Fig. 9a].

4. Claims 6 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruitt (US 6458076 B1) in view of Hirata (US 7591781 B2) in view of Harkrider (US 6328730 B1).

5. Regarding claim 6, Pruitt teaches

an internal treatment apparatus for a patient comprising

a flexible tubular body [14] to be introduced into a patient, said flexible tubular body including a center opening [20'] capable of inserting therethrough an endoscope

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for observing a target site, said center opening extending through said flexible tubular body from a center of a distal end face of said flexible tubular body [Fig. 5], said distal end face facing said target site and a plurality of circumferential holes [e.g. 21'-28'] through which surgical instruments can be inserted for performing a surgical procedure on said target site, each of the holes being distinct from the center opening and a body manipulating device [18] for manipulating said flexible tubular body from outside said patient. However, Pruitt fails to specifically teach the holes provided to extend through a side face [Figs. 9A, 9B] of said flexible tubular body at said distal end of said flexible tubular body and independent from the distal end face, as well as an endoscope manipulating device for manipulating an endoscope inserted in the center opening and a surgical instrument manipulating device for manipulating surgical instruments inserted into the circumferential holes.

Hirata teaches a flexible internal treatment apparatus having a plurality of lumens [91a] for inserting tools into a body lumen for treatment, wherein the outlets, which are plurality of circumferential holes [98a-c], are placed on lateral sides of a distal end of the apparatus [Fig. 9A, the distal end face being unlabeled solid end piece] such that tools inserted within the lumens can be extended from the sheath at any desired position in order to inspect other portions of the body lumen [col. 8, ll. 41-60].

It would have been obvious to one of ordinary skill in the art to modify the apparatus as taught by Pruitt with lateral circumferential holes as taught by Hirata to provide the additional advantage of allowing inserted tools to be extended from the

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tubular body in additional positions in order to allow for more flexible and varied treatment.

Harkrider teaches an internal treatment apparatus with multiple lumens for insertion of viewing instruments [col. 4, ll. 15-20] and other surgical tools [col. 4, ll. 28-35] for a similar purpose of allowing for more flexible and convenient treatment. Pruitt teaches a viewing instrument [43] inserted within one peripheral lumen [22, Fig. 2, by way of example]. Harkrider teaches placing an endoscope into the center axis may be preferential for getting a particular view of the treatment area, although allowing the endoscope to be placed in a peripheral lumen would provide alternate views as desired [col. 4, ll. 15-26]. It would have been obvious to one of ordinary skill to place the viewing optics of Pruitt in the center opening as taught by Harkrider to provide that desired view of the treatment area. Further, endoscopes are commonly known to have their own manipulation means, which can be considered the proximal end of the endoscope manipulatable by the user, and surgical instruments similarly are known to have their own manipulation means, therefore the manipulating devices for endoscope and surgical instruments are considered inherent.

Regarding claim 36, Pruitt in view of Hirata in view of Harkrider teach the flexible tubular body comprises a resiliently deflectable portion [14, 16, Fig. 1 of Pruitt], and a circumferential opening portion [where the holes of Hirata are located on Pruitt] includes said plurality of circumferential holes, and the circumferential opening portion passes through the apparatus body from a side face of the deflectable portion toward a proximal end face of the apparatus body [as seen in Hirata Fig. 9a].

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. US 6761685 B2 USPAT Adams; Ronald et al. Controllable endoscopic sheath apparatus and related method of use

9. US 5813976 A USPAT Filipi; Charles J. et al. Stabilizing instrumentation for the performing of endoscopic surgical procedures

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA CHEN whose telephone number is (571)272-3356. The examiner can normally be reached on Monday to Friday, 9AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victoria W Chen/
Examiner, Art Unit 3779

/John P Leubecker/
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